

always help one; that it would eliminate any danger to general health or assist in digestive processes, would help one to feel his best, would not cause shock or strain or weakening aftereffects and would be good for every member of the family; and that unusual benefits would be derived from its use, were false and misleading since it possessed no tonic properties but was merely a laxative; it would not accomplish the results claimed, it might cause shock, strain, and weakening aftereffects; it would not necessarily be good for every member of the family; and there was nothing unusual about any benefits it might give. (3) In that the statement "Weltone Laxative is labeled in compliance with the Federal Food, Drug and Cosmetic Act" was false and misleading.

On April 17, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS

717. Adulteration and misbranding of Endocrine Extract Formula Nos. 2, 131, and 157; misbranding of Colloidal Dextro Calcium Bleything. U. S. v. The Bleything Laboratories. Plea of guilty. Fine, \$520. (F. D. C. No. 4150. Sample Nos. 44102-E, 44425-E, 65833-E to 65835-E, incl.)

This case involved three shipments of endocrine extracts that were deficient in potency, and one of colloidal dextro calcium that contained a smaller amount of calcium than that indicated and implied in the labeling.

On April 28, 1942, the United States attorney for the Southern District of California filed an information against the Bleything Laboratories, a corporation at Los Angeles, Calif., alleging shipment within the period from on or about October 17, 1940, to on or about July 2, 1941, from the State of California into the State of Colorado of quantities of endocrine extracts that were adulterated and misbranded, and of colloidal dextro calcium that was misbranded.

Endocrine Extract Formula No. 2 was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since it was represented to contain in each 33 cc., 3 milligrams of the crystalline principle of thyroid and 20 milligrams of the crystalline principle of entire ovary; whereas it contained no detectable amount of the crystalline principle of thyroid or of entire ovary. It was alleged to be misbranded in that the statements in the labeling, "Endocrine Extract * * * For Sublingual Use * * * Extracted principles of glands from government inspected animals and distilled water. * * * Extracted Crystalline Principles of the following glands: Thyroid . . . 3 mgm. * * * Entire Ovary . . . 20 mgm.," were false and misleading.

Formula No. 131 was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since it was represented to contain in each 33 cc., 3 milligrams of the crystalline principle of thyroid and 10 milligrams of the crystalline principle of the male orchic gland; whereas it contained no detectable amount of the crystalline principle of the thyroid or of the male orchic gland. It was alleged to be misbranded in that the statements in the labeling, "Endocrine Extract * * * For Sublingual Use * * * Extracted principles of glands from government inspected animals and distilled water. * * * Extracted Crystalline Principles of the following glands: Thyroid . . . 3 mgm. * * * Male Orchic . . . 10 mgm.," were false and misleading.

Formula No. 157 was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain in each 33 cc., 3 milligrams of the crystalline principle of thyroid, 10 milligrams of the crystalline principle of the pineal gland, and 5 milligrams of the crystalline principle of the male orchic gland; whereas it contained no detectable amounts of the crystalline principles of the thyroid, pineal, or male orchic glands. It was alleged to be misbranded in that the statements in the labeling, "Endocrine Extract * * * For Sublingual Use * * * Extracted principles of glands from government inspected animals and distilled water. * * * Extracted Crystalline Principles of the following glands: Thyroid . . . 3 mgm. Pineal . . . 10 mgm. * * * Male Orchic . . . 5 mgm.," were false and misleading.

The colloidal dextro calcium was alleged to be misbranded; (1) In that the statements, (bottle label) "Colloidal Dextro Calcium Bleything * * * Dosage: One teaspoonful three times daily before meals. May be taken in milk or

fruit juices, if preferred. In pronounced cases dosage may be doubled for two weeks. Dosage for children is the same as for adults," were false and misleading since they represented and suggested that in the dosages recommended, it would supply the user with sufficient calcium to be of therapeutic value in cases of ordinary calcium deficiency and even in cases of pronounced calcium deficiency; whereas in the maximum daily dosage recommended, namely, 6 teaspoonfuls, it would supply not more than $\frac{1}{750}$ of the amount of calcium required daily by an adult human being, which would be inconsequential for therapeutic purposes. (2) In that the statement on the label, "1-20 of 1% Sodium Benzoate," was false and misleading since it represented that the article contained not more than $\frac{1}{20}$ of 1 percent of sodium benzoate; whereas the two shipments of the product contained $\frac{1}{4}$ and $\frac{1}{6}$ of 1 percent, respectively, of sodium benzoate.

On May 21, 1942, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$65 on each of the 8 counts of the information, totaling \$520.

718. Adulteration and misbranding of elixir iron, quinine, and strychnine. U. S. v. Richard G. Dunwody (R. G. Dunwody & Sons, Inc.). Plea of guilty. Fine, \$200. (F. D. C. No. 6455. Sample No. 48135-E.)

This product contained smaller amounts of tincture of iron citrochloride and quinine sulfate per fluid ounce than those declared on the label.

On May 1, 1942, the United States attorney for the Northern District of Georgia filed an information against Richard G. Dunwody, trading as R. G. Dunwody & Sons, Inc., at Atlanta, Ga., alleging shipment on or about April 14, 1941, from the State of Georgia into the State of Florida of a quantity of elixir iron, quinine, and strychnine which was adulterated and misbranded. It was labeled in part: "Tincture of Ferric Citrochloride 60 Minims Quinine Sulphate 4 grains."

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since the label represented that it contained not less than 60 minims of tincture of ferric citrochloride and 4 grains of quinine sulfate per fluid ounce; whereas it contained not more than 23.8 minims of tincture of ferric citrochloride and not more than 3.08 grains of quinine sulfate per fluid ounce. It was alleged to be misbranded in that the statements in the labeling which represented that it contained 60 minims of tincture of ferric citrochloride and 4 grains of quinine sulfate per fluid ounce were false and misleading.

On May 9, 1942, the defendant entered a plea of guilty; and on May 29, 1942, the court imposed a fine of \$200.

719. Adulteration of Estromone. U. S. v. Endo Products, Inc. Plea of guilty. Fine, \$250. (F. D. C. No. 2967. Sample Nos. 20916-E, 24259-E, 28450-E, 34073-E, 46129-E to 46131-E, incl., 46133-E, 46134-E, 86212-E.)

On February 20, 1942, the United States attorney for the Eastern District of New York filed an information against Endo Products, Inc., Richmond Hill, N. Y., alleging shipment within the period from on or about December 28, 1939, to on or about November 20, 1940, from the State of New York into the States of North Carolina, Pennsylvania, Maryland, and New Jersey of quantities of Estromone which was adulterated.

The article was alleged to be adulterated in that its strength differed from or its quality fell below that which it purported or was represented to possess since (1) six of the shipments consisted of tablets which were represented to possess a biological activity equivalent to that of 2,000 International Units of estrogenic hormone; whereas the tablets in five shipments were found to possess a biological activity equivalent to that of not more than 600 International Units of estrogenic hormone and those in the sixth shipment possessed a biological activity equivalent to that of not more than 900 International Units per tablet. (2) One shipment consisted of tablets which were represented to possess a biological activity equivalent to that of 4,000 International Units of estrogenic hormone per tablet; whereas they possessed a biological activity equivalent to that of not more than 1,800 International Units of estrogenic hormone. (3) The remaining shipments were represented to consist of estrogenic substances in oil possessing in each cubic centimeter a biological activity equivalent to that of 5,000, 10,000, and 2,000 International Units, respectively, of estrogenic substance; whereas they possessed a biological activity equivalent to the activity of not more than 1,990, 1,740, and 1,325 International Units, respectively, of estrogenic substance.

On April 29, 1942, a plea of guilty was entered on behalf of defendant and the court imposed a fine of \$250.